July27, 2020

Medrad, Inc.
George Lucas
Senior Regulatory Affairs Associate
8880 Evergreen Blvd. Nw
Minneapolis, Minnesota 55433

Re: K133023
Trade/Device Name: JETSTREAM XC 2.4/3.4
JETSTREAM XC 2.1/3.0
JETSTREAM SC 1.85
JETSTREAM SC 1.6
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II
Product Code: MCW, QEW

Dear George Lucas:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 27, 2014. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2020.07.27 08:20:47 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 27, 2014

Bayer Medical Care, Inc.
Mr. George Lucas
Senior Regulatory Affairs Associate
8880 Evergreen Blvd. NW
Minneapolis, MN 55433-8003

Re: K133023
Trade/Device Name: Jetstream Systems
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: July 21, 2014
Received: July 22, 2014

Dear Mr. Lucas,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133023

Device Name
JETSTREAM® XC 2.4/3.4; JETSTREAM® XC 2.1/3.0; JETSTREAM® SC 1.85; JETSTREAM® SC 1.6

Indications for Use *(Describe)*

The JETSTREAM System is intended for use in atherectomy of the the peripheral vasculature and to break apart and remove thrombus for upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

General Information:

Date of Summary Preparation:	August 26, 2014
Name and Address of Manufacturer:	Bayer Medical Care Inc. 9055 Evergreen Blvd NW Minneapolis, MN 55433-8003
Contact Person:	George Lucas Senior Regulatory Affairs Associate Phone: 763-717-1163 Fax: 763-780-2227
Device Trade Names:	JETSTREAM® XC 2.4/3.4 System JETSTREAM® XC 2.1/3.0 System JETSTREAM® SC 1.85 System JETSTREAM® SC 1.6 System
Common Name:	Peripheral Atherectomy Catheter
Regulation Number:	21 CFR 870.4875
Regulation Name:	Intraluminal Artery Stripper
Regulatory Class:	Class II
Classification Panel:	Cardiovascular
Product Code:	MCW

Performance Standards: Performance Standards do not currently exist for these devices. None are established under Section 514.

Device Description: The JETSTREAM Systems are rotational atherectomy catheter systems designed with either a fixed (JETSTREAM SC 1.85, JETSTREAM SC 1.6) or an expandable (JETSTREAM XC 2.4/3.4, JETSTREAM XC 2.1/3.0) cutting tip intended for use in debulking and treating vascular disease in the peripheral vasculature. Separate lumens within the Catheter allow for continuous aspiration and infusion during device use. Excised tissue, thrombus, and fluid are aspirated from the peripheral treatment site through a port in the Catheter tip to an external collection bag located on the Console. The distal portion of the Catheter also possesses infusion ports that provide continuous infusion of sterile saline during the atherectomy procedure.

The JETSTREAM Systems consist of two primary components: a Catheter with Control Pod and a Console, which are packaged separately. Each of these system components is described generally as follows:

- **JETSTREAM Catheter with Control Pod:** A sterile, single-use unit consisting of an electrically-driven Catheter with attached Control Pod. As with the predicate device, the identical JETSTREAM Catheter utilizes a differentially cutting tip and includes both aspiration and infusion capabilities and the Control Pod with Activation Handle provides a user interface with keypad controls. The unit, its electrical connectors, tubing, and aspirant collection bag are packaged in a single pouched tray.

- **PV Console:** A reusable compact PV Console, with two (2) peristaltic pumps for aspiration and infusion, power supply, system controller, keypad interface, and LED indicators for device operational status. The PV Console mounts on a standard I.V. stand and remains outside the sterile field during the procedure.

The purpose of this 510(k) is to add atherectomy lubricant as an optional procedure supply listed within the Instructions for Use (IFU). This modification applies to the entire family of JETSTREAM Systems.

Indications for Use: The JETSTREAM System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Substantially Equivalent Devices: Bayer Medical Care cites the following devices as the primary predicate devices for the aforementioned modification and substantial equivalence basis.

Primary Predicate Devices	MEDRAD Predicate 510(k)
JETSTREAM® XC 2.4/3.4 System	K130637
JETSTREAM® XC 2.1/3.0 System	
JETSTREAM® SC 1.85 System	
JETSTREAM® SC 1.6 System	

However, the design rationale for and device testing of the subject devices also includes references to the additional predicate devices listed in the table below:

Other Predicate Devices	MEDRAD/Pathway Medical Predicate 510(k)
JETSTREAM Systems (XC and SC family)	K122916
JETSTREAM Navitus® L System	K120242
JETSTREAM G3® SF 1.6 System	K111229
JETSTREAM Navitus® System	K110626
JETSTREAM G3® SF System	K101334
JETSTREAM G3® System	K101221
JETSTREAM G3® System	K093456
JETSTREAM G3® System	K092332
JETSTREAM G2™ NXT System	K091509
JETSTREAM Pathway PV™ Atherectomy System	K082186
Pathway PV™ Atherectomy System	K081328

Testing Summary: To demonstrate substantial equivalence of the subject JETSTREAM Systems to the predicate JETSTREAM Systems, the technological and performance characteristics were evaluated by completion of the following testing:

- System Reliability/Life Test
- Aspiration Efficiency & Crossing Time
- Material Liberation (Guidewire Teflon and Stainless Steel)
- Rotational Speed
- Accessory Compatibility
- Infusion & Aspiration Flow Rates
- Catheter Translation Over Guidewire (Aggressive Thrombus Test & Guidewire Challenge Blood Test)
- Catheter Aspiration Clogging Test
- Tip Cutting (Aorta Strip Test and Lumen Size Test)
- Cytotoxicity (this was done on Rotaglide alone, ViperSlide alone, Rotaglide exposed to the device and ViperSlide exposed to the device)
- Hemolysis (this was done on Rotaglide alone, ViperSlide alone, Rotaglide exposed to the device and ViperSlide exposed to the device)
- Acute Toxicity (this was done on Rotaglide alone, ViperSlide alone, Rotaglide exposed to the device and ViperSlide exposed to the device)

- FTIR Testing and analysis (this was done on Rotaglide alone, ViperSlide alone, Rotaglide exposed to the device and ViperSlide exposed to the device)

The results from these tests:

- demonstrate that the technological and performance characteristics of the subject JETSTREAM Systems are comparable to the predicate JETSTREAM Systems,

- support the safety and effectiveness of the modification that is the subject of this 510(k), and

- ensure the subject devices can perform in a manner equivalent to the predicate JETSTREAM Systems with the identical intended use.

Conclusion (Statement of Equivalence): The data and information presented within this submission (including *in vitro* bench testing) and the similarities between the subject and predicate devices support a determination of substantial equivalence, and therefore market clearance of the subject JETSTREAM Systems through this 510(k) Premarket Notification.